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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEPHEN A. JOHNSTON, KATHERINE STEMKE-HALE, KATHRYN F. SYKES, and BERNHARD KALTENBOECK

Appeal 2009-006341
Application 10/023,437
Technology Center 1600

Decided: January 27, 2010

Before TONI R. SCHEINER, DEMETRA J. MILLS, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for lack of enablement and lack of utility. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF CASE

The following claims are representative.

92. A method of immunizing an animal comprising the step of:
administering a Chlamydia psittaci antigen to an animal in an amount effective to induce an immune response against Chlamydia psittaci; wherein the Chlamydia psittaci antigen comprises the amino acid sequence as set forth as SEQ ID NO:7.

94. The method of claim 92, wherein the method further comprises the step of:
administering a second Chlamydia psittaci antigen to an animal in an amount effective to induce an immune response against Chlamydia psittaci; wherein the second Chlamydia psittaci antigen comprises the amino acid sequence as set forth as SEQ ID NO: 9, 13, 23, or 27.

Cited References

Sato et al., *Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization*, 273 SCIENCE 352-354 (1996).

Appellants rely on the following references:

Tang et al., *Genetic Immunization is a simple method for eliciting an immune response*, 356 NATURE 151-154 (1992).

Lorne A. Babink, *Broadening the approaches to developing more effective vaccines*, 17 VACCINE 1587-1595 (1999).

Ronald W. Ellis, *New technologies for making vaccines*, 17 VACCINE 1596-1604 (1999).

Chart provided during October 23, 2007 interview and submitted in October 26, 2007 Reply to Advisory Action correlating *C. psittaci* gene fragment numbers of Fig. 5 to CP4# designations to Fig. 6 and Table 2.

Declaration of Akira Takashima, M.D., Ph.D., dated March 10, 2005.

Declaration of Dr. Bernhard Kaltenboeck, dated April 17, 2007.

Declaration of Dr. Bernhard Kaltenboeck, dated August 8, 2007.

Grounds of Rejection

1. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.
2. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. § 101, as failing to comply with the utility requirement.

FINDINGS OF FACT

The findings of fact below are relevant to all rejections before us.

1. The appealed claims are directed to a method of immunizing an animal comprising the step of: administering a *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci,* wherein the *Chlamydia psittaci* antigen comprises the amino acid sequence as set forth as SEQ ID No. 7. Thus, the antigen in the claim is an amino acid and not a nucleic acid.

2. The Examiner finds that "[i]ndependent 92 in particular, reads on a product that exists in nature because it recites '...administering a *Chlamydia psittaci* antigen...'". (Ans. 3.)

3. The Examiner finds that:

> Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of immunizing an animal comprising the step of administering a genetic vaccine comprising pooled DNA clones or full-length genes and/or fragments from *Chlamydia psittaci* (see Example 8 and

> Example 9) and a protein vaccine comprising a pool of full-length proteins and/or a pool of protein fragments from *Chlamydia psittaci* (see Example 9) in an amount effective to induce an immune response against *Chlamydia psittaci;* does not provide enablement for a method of immunizing an animal comprising the step of administering a single *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci;* wherein the *Chlamydia psittaci* antigen comprises the amino acid sequence as set forth as SEQ ID Nos. 7, 9, 11 and 13 (examined sequences).

(Ans. 3.)

4. The Examiner finds that "[t]he specification has shown enablement for immunizing cattle with a pool of 14 DNA genes. See Example 8 and Table 4 of the instant specification. The specification has also shown enablement for a genetic vaccine comprising a pool of five protective full-length genes and/or gene fragments isolated in the gene screening process." (*Id.* at 4.)

5. The Examiner finds that "[t]he instant specification has further shown enablement for a protein vaccine which comprises full-length *Chlamydia psittaci* proteins and/or protein fragments. See Example 9 of the specification." (*Id.*)

6. The Examiner finds "that the vaccine compositions used to vaccinate the animals in the specification comprise pools of genes or proteins. Thus, one of skill in the art cannot ascertain whether one single gene or protein or a combination of genes or proteins provide the protection described in Examples 8 and 9 of the instant specification." (Ans. 4.)

7. The Examiner finds that it "is unclear as to *which specific genes* and *which specific proteins* are present in the vaccine compositions of Examples 8 and 9 of the instant specification." (*Id.*)

8. The Examiner finds that the Specification

> [H]as only provided one example, Example 8, that relates specifically to vaccination of animals. However, this example immunizes the animals with a *pool of 14 gene clones*. Thus, the specification discloses a method of immunizing animals comprising a pooled DNA vaccine and *not a method of immunizing an animal comprising administering a Chlamydia psittaci protein vaccine comprising administering one single Chlamydia psittaci* antigen as recited in the instant claims.

(Ans. 5.)

9. The Examiner finds that:

> One of skill in the art would not reasonably conclude that a DNA vaccine and a protein vaccine would behave in the same manner when administered to an animal. It should be noted that the claimed method is directed to immunizing an animal with a single *Chlamydia psittaci* antigen in an amount that is effective in inducing an immune response to the administered *Chlamydia* antigen. Sato et al *(Science, Vol. 273, July 19, 1996, p.352-354)* teach that DNA vaccines do not necessarily induce an immune response to the encoded antigen (see the Abstract).

(*Id.*)

10. The Examiner concludes that,

> [G]iven the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of a immune reaction to a specific antigen, the specification, as filed, does not provide enablement for a method of immunizing an animal comprising

> administering a *Chlamydia psittaci* protein vaccine comprising administering *one single Chlamydia psittaci* antigen.

(Ans. 5.)

11. According to Appellants, the Specification discloses that "the inventors conducted a series of experiments with mice as detailed in Fig. 5 in the associated discussion of the present application (*see*, pp. 64-89)." (App. Br. 16.)

12. Appellants note that the experimental procedure of Fig. 5. "is also discussed in the Declarations of Dr. Kaltenboeck" annexed in the evidence appendix to the Brief. (*Id.*)

13. Appellants find that "[a]s described on pages 70-72 of the application, clones that contained *Chlamydia psittaci* DNA inserts that coded for open reading frames of more than 50 amino acids were identified in three rounds of screening and were considered to be potential vaccine candidates by the inventors (*see, e.g.*, p. 70; Fig. 3). . . . [F]ragments were identified and those gene fragment[s] were tested in the experiment of Fig. 5 of the present application on mice." (*Id.*)

14. Appellants contend that the experiment of Fig. 5 of the Specification, pages 70-72,

> [I]ncluded four controls, including a positive control for genetic immunization wherein the pool of all the fourteen identified gene fragments having more than 50 amino acids was administered, a negative control wherein a pool of inserts less than 50 amino acids long was administered, a control vaccination with low dose *Chlamydia psittaci* infection that elicited a strong specific immunity against *Chlamydia psittaci* and a challenge control of mice that were completely unexposed to *Chlamydia psittaci*.

(App. Br. 16.)

15. According to Appellants, "[t]he results of the Fig. 5 experiment are detailed at pp. 70-72 and in Fig. 5 of the present application. The results indicate that genetic immunization with CP4#s 1 to 5 achieved protection from *Chlamydia psittaci* better than what is achievable from natural low dose vaccination." (*Id.*)

16. Appellants contend that, in Fig. 5 of the Specification, "[t]he positive genetic immunization control pool (greater than 50 amino acids) also protected better than what is naturally achievable." (*Id.*)

17. Appellants further contend:

> [F]rom the experiment of Fig. 5, particular gene fragments that were effective to induce an immune response against *Chlamydia psittaci* were identified. In fact, the most highly protective gene identified in Fig. 5 was Gene No. 1 of Fig. 5 which corresponds to CP4#1 in Table 2 in Fig. 6 of the present application. The sequences of all 14 plasmids inserts were analyzed, the full *C. psittaci* genes isolated, the position of the fragments within the full genes determined, and the full genes characterized for gene terminology and function by homology search. These results are shown in Fig. 6, and are described in Example 6 with a summary in Table 2 (p. 74) and a complete listing of all sequences with SEQ ID Nos. are provided in Table 3 (p. 75-80) of the present application.

(*Id.*)

18. Appellants further contend:

> Thus, CP4#1 was sequenced and is represented by Sequence ID Nos. 6-9, wherein Sequence ID No. 6 is the original DNA gene fragment, Sequence ID No. 7 is the polypeptide fragment corresponding to the gene fragment of No. 6, Sequence ID No. 8 is the full length DNA gene that includes the gene fragment of Sequence ID No. 6; and

> Sequence ID No. 9 is the full length polypeptide sequence of Sequence ID No. 8.

(App. Br. 16-17.)

19. Appellants further contend that "Fig. 5 demonstrates a specific method of immunizing an animal including the step of administering a *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci*, and wherein the antigen comprises the sequences set forth in Sequence ID No. 7." (*Id.* at 17.)

20. Appellants further contend:

> The state of the prior art of making and using antigenic peptides is well known using PCR techniques for amplifying a coding sequence of the DNA of a fragment, cloning these into expression vectors, expressing the protein in any recombinant protein expression system and then purifying as a recombinant protein.

(*Id.*)

21. Appellants further contend that "claim 92 recites that the antigen comprises SEQ ID No.7. SEQ ID No. 7 is the amino acid sequence of the most highly protective gene fragment identified in Examples 1-4 in Fig. 5, namely, Fig. 5, Round 4, Gene Fragment No. 1. i.e., CP4# 1." (*Id.*)

ISSUE

The Examiner argues that:

> [T]he specification, while being enabling for a method of immunizing an animal comprising the step of administering a genetic vaccine comprising pooled DNA clones or full-length genes and/or fragments from *Chlamydia psittaci* (see Example 8 and Example 9) and a protein vaccine comprising a pool of

> full-length proteins and/or a pool of protein fragments from *Chlamydia psittaci* (see Example 9) in an amount effective to induce an immune response against *Chlamydia psittaci;* does not provide enablement for a method of immunizing an animal comprising the step of administering a single *Chlamydia psittaci* antigen to an animal in an amount effective to induce an immune response against *Chlamydia psittaci;* wherein the *Chlamydia psittaci* antigen comprises the amino acid sequence as set forth as SEQ ID Nos. 7, 9, 11 and 13 (examined sequences).

(Ans. 3.)

As noted above, Appellants contend that evidence of record supports enablement, particularly that in Fig. 5 and its description in the Specification. (App. Br. 17.)

The issue is: Have Appellants demonstrated error in the Examiner's enablement rejection by showing the evidence presented in Fig. 5 supports enablement of the pending claims?

PRINCIPLES OF LAW

The examiner bears the initial burden of showing nonenablement. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "[E]nablement requires that the specification teach those in the art to make and use the invention without 'undue experimentation.' . . . That *some* experimentation may be required is not fatal; the issue is whether the amount of experimentation required is 'undue.'" *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991) (emphasis in original). Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in

which the experimentation should proceed. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Considered factors include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

Thus, "[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Id.*)

"The enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)).

A claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984); *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976); *In re Cook*, 439 F.2d 730, 732 (CCPA 1971).

ANALYSIS

Appellants contend that the evidence of record supports enablement, particularly that in Fig. 5 of the Specification. (App. Br. 17.)

We agree with the Appellants that the evidence of record supports enablement, particularly that in Fig. 5 of the Specification. We are not

persuaded by the Examiner's fact finding in view of the evidence presented in Figure 5 of the Specification.

The Examiner relies on Sato as evidence that DNA vaccines do not necessarily induce an immune response to the encoded antigen. (Ans. 5.) However the claims before us are directed to a method of immunizing an animal with an antigen which comprises an amino acid sequence and the claim is not directed to administering a DNA vaccine.

Thus, the Examiner has failed to provide evidence that the antigens administered in Figure 5 and the associated results discussed in the Specification, pages 70-72, are not protective or would not have been considered protective by one of ordinary skill in the art. It would reasonably appear from Appellants data in Figure 5, that a protective immune response was obtained using numerous fragments encoding amino acids, as claimed.

CONCLUSION OF LAW

Appellants have demonstrated error in the Examiner's enablement rejection showing the evidence presented in Fig. 5 supports enablement of the pending claims.

2. Claims 92, 94-95 and 104-121 are rejected under 35 U.S.C. § 101, as failing to comply with the utility requirement.

PRINCIPLES OF LAW

The burden is on the examiner to set forth a prima facie case of unpatentability. *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002).

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.

Diamond v. Diehr, 450 U.S. 175, 188-89 (1981). For claims including such excluded subject matter to be eligible for patent protection, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. *Id.* at 187 ("*application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").

> While abstract ideas, natural phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of section 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract idea, natural phenomenon, or law of nature, and not for the abstract idea, natural phenomenon, or law of nature itself.

MPEP § 2106, Patentable Subject Matter Eligibility, Section IV, C. (Rev. 6, Sept 2007).

ANALYSIS

The Examiner argues that the claims should be limited to an isolated or purified *Chlamydia psittaci* antigen because they read on a product that

exists in nature. (Ans. 3.) However, the claims in the present case are limited to a method of immunizing an animal, not a natural composition. The Examiner has not met the burden of establishing a prima facie case of unpatentability of the method before us as the Examiner has failed to present evidence that the claimed method exists in nature. The utility rejection is reversed.

REVERSED

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